View of NCT00103857 on 2006_02_22

ClinicalTrials Identifier: NCT00103857
Updated: 2006_02_22

Descriptive Information

Brief title An Investigational Drug Study in Patients With Type 2 Diabetes Mellitus

Official title A Multicenter, Randomized, Double-Blind Factorial Study of the Co-Administration of MK0431 and Metformin in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control

Brief summary

The purpose of this study is to determine the safety and effectiveness of an investigational drug in patients with Type 2 Diabetes Mellitus (a specific type of diabetes).

Detailed description

Duration of Treatment: 5.5 months

Phase Phase 3
Study type Interventional
Study design Treatment
Primary outcome Measure: HbA1c
Secondary outcome Measure: FPG; fructosamine; glucose, insulin, and C-peptide profiles measured by MTT; proporation of patients meetings pre-specified rescue criteria; lipid panel; body weight; waist circumference; and appetite assessment.
Condition Type 2 Diabetes Mellitus
Intervention Drug: MK0431, sitagliptin phosphate
Intervention Drug: Comparator: metformin 500 mg bid
Intervention Drug: Comparator: metformin 1000 mg bid
Intervention Drug: Comparator: placebo

Recruitment Information

Status No longer recruiting
Criteria

Inclusion Criteria:
- Patients between the ages of 18 and 78 with Type 2 Diabetes Mellitus (a specific type of diabetes).

Exclusion Criteria:
- Patients who do not have Type 2 Diabetes Mellitus (a specific type of diabetes).

Gender Both

Minimum age	18 Years
Maximum age	78 Years
Healthy volunteers	No
Expected enrollment	1050

Administrative Data

Organization name	Merck
Organization study ID	2005_003
Sponsor	Merck
Health Authority	United States: Food and Drug Administration